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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,025	06/30/2003	Hirokazu Ohbayashi	239546US0CONT	8296

22850 7590 11/02/2006

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ALEXANDRIA, VA 22314

EXAMINER
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CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/608,025	OHBAYASHI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jacob Cheu	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27, 32-38 and 47-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27, 32-38 and 47-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

Applicant's amendment filed on 4/8/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-26, 28-31, 39-46, 41-46, 51-52 are cancelled.
2. Claims 27, 32-38 and 47-50 are under examination.

#### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 27 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 16 and 24 of U.S. Patent No. 6,613,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because The US Patent 6,613,564 directs to an carrier-enzyme-protein complex comprising (1) a carrier (2) enzyme conjugates to the carrier (3) protein bind to the enzyme and said protein is not directly conjugated to said carrier, whereas the instant applicant directs to a product comprising an carrier-enzyme-protein complex comprising all the features, including (1)-(3) as recited in the 6,613,564 patent. The patent is for an carrier-enzyme-protein complex, the application is for a product comprising an carrier-enzyme-protein complex. Although claims are not identical, they are not patentably distinct from each other. Furthermore, carrier recited in the instant claim is “water-soluble” and the US 6613564 also teaches use of “water-soluble” carrier, such as peptide polymer, polylysine or polysaccharide as in claims 5-7.

#### ***Withdraw Prior Art Rejections***

3. The rejections of claims 27, 32-36, 38-40, 47-52 under 35 U.S.C. 102(b) as being anticipated by Johnston et al. are withdrawn because Johnson et al. do not use “water-soluble” carrier, rather Johnston et al. teach using dextran beads, i.e. water-insoluble, for conjugating enzyme. Furthermore, the structure of the immunocomplex taught by Johnston et al. is different from the instant invention because the enzyme conjugated with biotin, not a protein.

4. The rejections of claims 27, 32-36, 38-40 and 47-52 under 35 U.S.C. 102(e) as being anticipated by Ohbayashi et al. are withdrawn because the carrier taught by Ohbayashi et al. directly conjugates with the protein, not as the instant recited structure, e.g. carrier-enzyme-protein.

#### ***Double Patenting***

5. The Double Patenting rejection is re-enforced in this Office Action. The reasons are outlined above. On 4/28/2006, applicant's Remarks stressed that the amended feature, “a water-soluble carrier” can distinguish from the Double Patenting rejections in view of U.S. Patent No.

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6,613,564. However, the carrier used in the U.S. Patent No. 6,613,564 is also "water-soluble", such as peptide polymer, polyssacharide or polylysine (See claims 5-7).

***Conclusion***

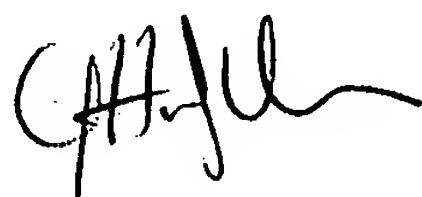
6. Claims 32-38 and 47-50 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

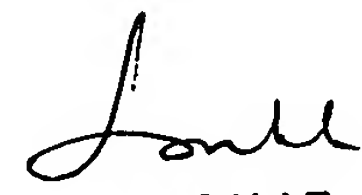
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu  
Examiner



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October 26, 2006

  
LONG V. LE 10/27/06  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600